REMARKS

In view of the following remarks, the Examiner is requested to allow Claims 1-21, as well as newly presented Claim 22, the only claims pending and under examination in this application.

Claim 1 has been amended to specify that the "vaginal indwelling thermometer is configured to be left in a vagina of a subject for a long period of time without causing discomfort to said subject and without being easily lost." Support for this amended is found on page 1, 4th full paragraph and page 6, second full paragraph, among other locations. In addition, support for new Claim 22 can be found on page 10, 4th full paragraph. As the above amendments introduce no new matter, their entry by the Examiner is respectfully requested.

Claim Rejections – 35 U.S.C. § 102

Claims 1-6, 9-11 and 19-21 have previously been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Nishimura (USPN 5,137,028).

An element of the rejected claims is an indwelling vaginal thermometer that is configured to be left in a vagina of a subject for a long period of time without causing discomfort to said subject and without being easily lost.

An "indwelling thermometer" is a term widely known in veterinary practices and in animal husbandry and, as stated in the description of the present application refers to a thermometer which is configured to be left in the body for a long period of time, without causing unnecessary discomfort to the animal or the user. Indwelling thermometers indwell in a body cavity such as the ear, cheek, rectum or vagina or are implanted into the subject animal or user.

"The term "indwelling thermometer" is known to the person skilled in the art as these links show:

http://www.safe-practices.org/1V2/SafePractice2.pdf

http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=27359

http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8339584&dopt=Abstract". Indwelling thermometers are known at least in surgery where they are used to monitor the core body temperature of a patient during long surgical procedures.

As defined by the Merriam-Webster Online Dictionary, the term indwelling means: left within a bodily organ or passage to maintain drainage, prevent obstruction, or provide a route for administration of food or drugs.

In maintaining the rejections of record, the Office continues to assert that Nishimura discloses an "indwelling" thermometer that is inserted into a body for a period of minutes (e.g., five minutes). The Office asserts that because minutes are a long period of time when compared to seconds, Nishimura discloses an indwelling thermometer as recited in the Applicants' Claim 1.

The Federal Circuit has taught (as acknowledged and followed by the MPEP at 2111.01) that that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (discussed below); Chef America, Inc. v. Lamb-Weston, Inc., 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004) In addition. "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips v. AWH Corp., *>415

F.3d 1303, 1313<, 75 USPQ2d 1321>, 1326< (Fed. Cir. 2005) (en banc). Sunrace Roots Enter. Co. v. SRAM Corp., 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003).

In the present case, the term "indwelling thermometer" has a recognized meaning in the art as evidenced by the references cited and the dictionary definition given. Specifically, the term "indwelling thermometer" in the claim means a thermometer which is configured to be left in the body for a long period of time, without causing unnecessary discomfort to the animal or the user.

Accordingly, the claims are directed to an indwelling vaginal thermometer that is configured to be left in a vagina of a subject for a long period of time without causing discomfort to said subject and without being easily lost.

As demonstrated below, Nishimura fails to teach, much less suggest, such a thermometer. The thermometer described in Nishimura is not and cannot be indwelling. The thermometer described in Nishimura is clearly not indwelling: it is used for short periods of time - not long periods. In support of this assertion the Examiner's attention is directed to claims 2 and 3 of the corresponding European patent (EP 0424102 B1 – attached) where the "predetermined time" is defined as 30 seconds and 5 minutes, respectively. This is not long enough to be considered indwelling by the person skilled in the art.

Additionally, using the Nishimura device, the user is required to press buttons on the device in order to record the temperature, indeed, according to column 6, lines 10 to 17 two switches need to be depressed; clearly this would be physically impossible with an indwelling thermometer.

Furthermore, the device described in Nishimura comprises an alarm to ensure that temperature readings are taken at 24 hour intervals (± 5 minutes). This feature would not be needed with an indwelling thermometer and again directs one to the conclusion that Nishimura does not and cannot describe an indwelling thermometer.

As such, Nishimura does not teach or suggest an indwelling vaginal thermometer that is configured to be left in a vagina of a subject for a long period of time without causing discomfort to said subject and without being easily lost.

Therefore, Nishimura does not anticipate the claimed invention and we respectfully request that the 35 U.S.C. § 102(b) rejection of Claims 1-6, 9-11 and 19-21 be withdrawn.

Claim Rejections – 35 U.S.C. § 103

Claims 7-8 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nishimura in view of Nollen (USPN 3,895,523).

According to the MPEP § 706.02 (j), to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Claims 7 and 8 ultimately depend from Claim 1. As set forth above, an element of the rejected claims is an indwelling vaginal thermometer that is configured to be left in a vagina of a subject for a long period of time without causing discomfort to said subject and without being easily lost. As set forth above, Nishimura is deficient for failing to

teach an indwelling vaginal thermometer that is configured to be left in a vagina of a subject for a long period of time without causing discomfort to said subject and without being easily lost. As Nollen was cited for its teaching of a disposable thermometer that includes a dye and Vaseline, it fails to remedy the teachings of Nishimura. Therefore, a *prima facie* case of obviousness has not been established because the cited combination fails to teach every element of the rejected claims, namely, an indwelling vaginal thermometer that is configured to be left in a vagina of a subject for a long period of time without causing discomfort to said subject and without being easily lost. As such, this rejection may be withdrawn.

Claims 12-13 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nishimura in view of Hof *et al.* (USPN 4,345,470). As set forth above, Nishimura is deficient for failing to teach an indwelling vaginal thermometer that is configured to be left in a vagina of a subject for a long period of time without causing discomfort to said subject and without being easily lost. As Hof was cited for its teaching of an indicator means that is heat sensitive and changes color in response to a temperature change, it fails to remedy the teachings of Nishimura. As such, this rejection may be withdrawn.

Claims 14-21 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nishimura in view of Weiland (USPN 5,499,631).

Claims 14-18 are directed to a kit of thermometers. The kit includes a series of thermometers, wherein each thermometer detects a different predetermined threshold temperature across a range of temperatures. The thermometers are vaginal indwelling thermometers that are configured to be left in a vagina of a subject for a long period of time without causing discomfort to said subject and without being easily lost.

The Office acknowledges that Nishimura only discloses a single temperature sensing means. The Office, therefore, relies upon Weiland to remedy the deficiencies

of Nishimura. Weiland, however, does not teach a kit of thermometers that includes a plurality of thermometers wherein each thermometer detects a different predetermined threshold temperature across a range of temperatures. Rather, Weiland teaches a test probe that includes multiple test electrodes which are attached to the test probe. The primary function of the test electrodes is to measure electrical conductivity. Hence, the different test electrodes disclosed in Weiland do not detect different predetermined threshold temperatures across a range of temperatures as recited in the Applicants' claims. Accordingly, as neither Nishimura nor Weiland teach a plurality of thermometers wherein each thermometer detects a different predetermined threshold temperature across a range of temperatures, the recited combination fails to teach every element of the rejected claims.

Furthermore, as demonstrated above, Nishimura fails to teach or suggest an indwelling vaginal thermometer that is configured to be left in a vagina of a subject for a long period of time without causing discomfort to said subject and without being easily lost. Weiland fails to make up this deficiency.

With respect to Claims 19 – 21, the Office has not set forth where the elements of the rejected claims are taught or suggested by the recited combination. Further, Claims 19 – 21 ultimately depend from Claim 1. As set forth above, Nishimura is deficient in that it fails to teach every element of rejected Claim 1. As Weiland was cited solely for its teaching of a kit of multiple sensing means it fails to remedy the deficiencies of Nishimura.

Therefore, a *prima facie* case of obviousness has not been established. Accordingly, in view of this, the Applicant respectfully requests that the 35 U.S.C. § 103(a) rejection of Claims 14 – 21 be withdrawn.

Claim 15 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nishimura in view of Weiland and further in view of Nollen.

Claim 15 depends from Claim 14. An element of Claim 14 is a kit that includes a series of thermometers, wherein each thermometer detects a different predetermined threshold temperature across a range of temperatures. As described above, the combination of Nishimura and Weiland is deficient in that it fails to teach every element of the rejected claims, namely, a kit that includes a series of thermometers, wherein each thermometer detects a different predetermined threshold temperature across a range of temperatures. Nollen as well does not teach this element. Accordingly, the cited combination fails to teach every element of the rejected claims. Therefore, a *prima facie* case of obviousness has not been established. Accordingly, in view of this, the Applicant respectfully requests that the 35 U.S.C. § 103(a) rejection of Claim 15 be withdrawn.

Finally, new Claim 22 is patentable over the cited art for at least the reasons provided above.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Bret Field at (650) 833-7770.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number STHP-018.

Respectfully submitted,

BOZICEVIC, FIELD & FRANCIS LLP

Date: April 20, 2007

By: _____
Bret Field
Registration No. 37,20

Encs:

- **http://www.safe-practices.org/1V2/SafePractice2.pdf**
- **http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=27359**
- **http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8339584&dopt=Abstract"**
- EP 0424102 B1

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Volume 1, No.2

SAFE in Patient Care

Helping to promote a culture of safety

Physicians have recognized fever as a sign of illness since several thousand years before Christ. In the late nineteenth century, bacteria and other microorganisms were identified as able to induce fever, but how they did so was unknown. Clinical thermometry became an accepted clinical diagnostic resource when Carl Wunderlich published research findings of body temperature and established a range of normal temperature. A recent focus on patient safety standards by JCAHO has prompted clinicians to evaluate the safety of thermometry in their clinical environment. The hazards of clinical thermometry continue to change as technology and patient acuity become more complex. In her article, Dr. Holtzclaw explains while thermometer breakage and displacement have been the primary concerns for safety, however more attention should be focused on factors that affect the correct interpretation of thermometer readings.

Measurement of body temperature is a crucial clinical assessment in the care of acutely ill neonates, infants, and children. Acutely ill children require frequent and repeated temperature measurement, and accuracy and safety are paramount considerations. In their article, Ms. Kline and Martin discuss the safety issues in neonatal and pediatric thermometry.

SAFE

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This issue's commentary:
Safeguarding Patients Through Certification
by Jan Foster PhD, RN, CNS, CCRN

Monitoring Body Temperature in Critical and Acute-care Settings

By Barbara J. Holtzclaw, PhD, RN, FAAN

Safe surveillance of body temperature in seriously ill patients requires a level of caution that is often underestimated. The hazards of clinical thermometry continue to change as technology and patient acuity become more complex.

Historically, thermometer breakage and displacement have been the primary concerns for safety, while less attention has been focused on factors that affect the correct interpretation of thermometer readings. Confusion and false expectations have surrounded the use of newer temperature-measuring devices, affecting their interpretation, and care decisions related to temperature change are often inconsistent or faulty.

A review of current practices and literature related to temperature monitoring shows safety concerns in the following areas:

- injury or infection hazards posed by patient/thermometer contact
- thermometers as a source of iatrogenic infection
- incomplete understanding and false expectations of device capabilities
- inconsistent calibration and reliability checks of measuring devices
- few training and guideline sources for correct technique, interpretation, or troubleshooting of thermometric devices
- underuse of research on dynamics of temperature change in the critically ill

This article presents these problems within the context of accident and incident prevention. It discusses resources and suggestions for reducing risk factors in clinical situations.

Safe surveillance of body temperature in seriously ill patients requires a level of caution that is often underestimated.

Hazards of patient/thermometer contact

Glass thermometers

Most intrusive thermometric devices are placed in body orifices with fragile mucous membranes, which increases the potential for tissue injury. Indeed, the injury of glass breakage and risk of mercury toxicity to patients and caregivers are among the main reasons that traditional mercury-containing thermometers are no longer used in most clinical settings.

Safety concerns have launched a growing movement to ban the use of glass thermometers in the USA and other countries.[1,2] The small size and smooth handling end of glass thermometers makes it difficult for caregivers to maintain a firm grasp. These thermometers can be easily lost in the rectum, vagina, or urethra. Accidental breakage, swallowing, or migration of glass thermometers constitutes a medical emergency, requiring surgical or therapeutic intervention to treat mercury toxicity, repair lacerations, or extract a device lodged in an organ wall. Exposure to mercury vapors after a thermometer breaks requires evaluation by site-support personnel to assure that caregivers and patients have not been affected.

Risk of tissue injury

Risk of injury to the patient's skin or delicate mucous membranes remains a concern when caregivers insert any thermometric

Continued on page 4

Supported by an educational grant from Kendall, a business unit of Tyco Healthcare Group LP

Hazards in Neonatal and Pediatric Thermometry

By Andrea M. Kline, RN, MS, PCCNP, CPNP, CCRN, and Sarah A. Martin, RN, MS, PCCNP, CPNP, CCRN

Measurement of body temperature is a crucial clinical assessment in the care of acutely ill neonates, infants, and children. Temperature measurement is one important indicator of an alteration in the child's clinical status. The presence of fever may warrant additional laboratory and diagnostic testing or changes in the child's treatment plan.

A recent focus on patient safety standards by the Joint Commission on Hospital Accreditation of Healthcare Organizations (JCAHO) has prompted clinicians to evaluate the safety of thermometry in their clinical environment. Acutely ill children require frequent and repeated temperature measurement, and accuracy and safety are paramount considerations. This paper focuses on the safety of neonatal and pediatric thermometry.

Thermoregulation

Variations in the temperature of blood bathing the preoptic area of the hypothalamus, the body's temperature-control center, determine the physiological response in maintaining homeostasis.[2,3] This natural process is known as thermoregulation.

Almost 40 years ago, researchers measured numerous body sites with calorimetry and sensitive thermocouples to show that the hypothalamus controls sweating and peripheral vasodilation in response to warm stress.[3] Cold stress responses, such as increased heat production and peripheral vasoconstriction, are mediated by peripheral and central thermoreceptors.[3]

Since it is impractical to measure temperature at the hypothalamus, body sites that most closely approximate temperature changes in the hypothalamus or "core" provide the most accurate readings.[3]

Fever

Fever is an abnormal elevation of temperature in response to a number of pathologic conditions. There are many accepted definitions of fever; in pediatrics, there is a lack of consensus of what constitutes normothermia versus fever. Reference values for rectal temperature measurements in children are 37.0 to 37.3 degrees Celsius(°C). The suggested reference values for normothermia in the neonate are 36.5-37.5°C for the term baby and 36.3-36.9°C for the preterm baby.

A variety of biologic processes cause fever in the pediatric population. Some are infectious; others, non-infectious. Non-infectious etiologies can be as life-endangering as infectious ones. Non-infectious etiologies include adrenal insufficiency, thyroid storm, heat stroke, exercise, neurologic pathology, environmental exposure (e.g., heat lamps, air mattresses), medication administration, and malignant hyperthermia.[4] Neonates, however, tend to become hypothermic when assaulted with biologic processes.

> The tympanic membrane is unaffected by ambient air temperature, mouth breathing, oral intake, or insulation by stool.

Fever pathology

Cytokine release in the body, particularly interleukin (IL)-1, IL-6, and tumor necrosis factor (TNF)-alpha, play a central role in fever formation.[5] These cytokines bind to their unique receptors, located near the anterior hypothalamus, promoting the release of prostaglandin E.[2] Ultimately, this small lipid mediator crosses the blood-brain barrier, provoking responses that decrease heat loss and increase heat production.

A small population of acutely ill patients may experience increased sympathetic activity and heat production, resulting in hyperthermia.[5]

Routes of administration

Body temperature has traditionally been measured by different routes. Pulmonary artery temperature assessment has been described as the gold standard; however, it is impractical in children, as pulmonary artery monitoring is rarely done in this group of patients. Some temperature measurements, including esophageal, bladder, tracheal, and nasopharyngeal, are reserved for patients in the operating room (OR) or intensive care unit (ICU) due to their invasive nature.

In children, body temperature is usually assessed by rectal, sublingual, axillary, tympanic, or skin routes. The axilla and skin temperature routes are used in neonates. Each route has hazards and the risk of inaccuracy.

Oral

The oral route is common and generally well-accepted for older children. Oral thermometers have limited use in infants and young children due to issues of cooperation and appropriate mouth seal. Inaccurate placement, drinking, eating, and smoking within 15 minutes of measurement may alter the oral temperature value. Results may take several minutes and accuracy depends on the mouth being closed – a challenge for infants and young children.

Oral measurement may reflect changes in blood flow to the lingual or external carotid arteries and not the child's core temperature. Oral temperature values may vary up to 0.6°C in various sublingual regions, unless the thermometer is placed accurately in the posterior sublingual pocket.[3]

Axillary

The main advantage of this route is ease of access.

The axilla is not located near a major artery; therefore, fluctuations in core temperature may not be accurately assessed. Axillary measurements may be more than 1°C lower than core temperature.[6] It may take several minutes to obtain an accurate reading.

This route can be useful to track temperature trends in infants and children. Toddlers are more accepting of the axillary route than the tympanic-membrane route.[8] Mercury-containing glass, digital, infrared, or dot matrix thermometers can be used to obtain axillary temperature.

Rectal

The rectal route is the gold standard for noninvasive temperature assessment in children.

While widely accepted, this route has drawbacks. Inaccuracies in rectal temperature readings may be related to site of measurement within the rectum, presence of stool, and blood flow to the abdominal region. Rectal temperatures are slow to change, as compared to blood temperatures.[3,6,7,9] Even at steady state, rectal temperatures differ significantly from pulmonary artery temperatures.[9] Parental perceptions of abuse, embarrassment, and discomfort are associated with rectal-temperature measurement. Due to the short length of the rectum and the increased risk of perforation, this route is not recommended for use in the neonate.

Tympanic

Tympanic thermometry measures infrared radiation emitted from the tympanic membrane. This membrane is well-perfused and

located merely 3.5 mm from the hypothalamus, the body's temperature regulator. This location may be ideal for measuring body temperature.[3,6,8,9]

This route is preferred by some parents and is more accepted by some pediatric patients.[6,8] The tympanic membrane is unaffected by ambient air temperature, mouth breathing, oral intake, or insulation by stool. Temperature-measuring time is less than 2 seconds with most devices, making it quick and convenient, even for uncooperative children.

Some evidence suggests that this route may not be accurate in infants less than 3 months of age due to their short ear canal.

The thermometer has disposable covers, reducing concerns of infection transmission. It is designed to prevent deep penetration in the ear canal to minimize the risk for perforation.[6] Wax in the ear canal, presence of myringotomy tubes, acute otitis media, and otitis media with effusion do not appear to affect temperature assessment.[3,6,7] Purulent aural discharge is a contraindication to using this method of thermometry.[6] The thermometer does not come into contact with mucus membranes.

Temporal artery

Two devices that can be used for this route of temperature assessment are the infrared scanner and dot-matrix or liquid-crystal strip (see below). This route is rapid, delivering data in seconds, and is well tolerated in infants and children. It may be more accurate in children than adults, who have a thicker layer of skin over the temporal artery, which has an impact on temperature results.[9,10]

Physiological states that involve vasoconstriction, which occur in post-cardiac surgery patients, or high levels of catecholamine release may falsify data, causing lower readings.[10]

Types of thermometers

Infrared scanners

A noninvasive infrared scanner detects the highest temperature by scanning, presumably over the temporal artery.[10] This new technology has received mixed reviews in the limited research. Its disadvantages include the inability to obtain a reading at all and the potential for error when the child perspires on the forehead.[10]

Dot matrix thermometers

These single-use, disposable devices are available for several routes, including oral, axillary, and temporal artery. Each dot is filled with a chemical mixture that is formulated to melt and change color at a certain temperature.

These devices may limit the risk of cross contamination between children. However, some evidence suggests that, even with disposable devices, there is a risk of cross contamination due to contact with caregivers' gloves or hands.

Limited research has documented the accuracy of dot-matrix thermometry. Infants and children who are crying are not candidates for oral dot-matrix devices, as they are unable to seal their mouths around the thermometer. It takes 60 seconds for an oral reading and 3 minutes for an axillary reading.

When these thermometers are exposed to temperatures of 86° Fahrenheit or 30°C , the dots turn blue and the thermometers must be reset. They must be placed in a freezer for one hour, then remain at room temperature for one day before reuse. Accuracy is not affected by this procedure.

Single-use thermometers are not as cost-effective as reusable ones.

Safety issues

Mercury-containing thermometers: Do risks outweigh benefits?

The use of mercury-containing glass thermometers, despite alternate means of thermometry, is still the standard for obtaining temperatures in many healthcare settings.[11] These thermometers have a 25% error rate after a use or shelf life of 8 months.[12]

The main concern with these devices is the possibility of mercury exposure and poisoning on breakage. Recently proposed federal legislation, Bill S.616, calls for banning the sale of mercury-containing glass thermometers, except by prescription, and for provision of federal monies for state and local exchange programs. This bill calls for a plan for long-term management of mercury, including long-term storage and sequestration, and for minimizing the use of mercury-containing products.

In a recent position statement, the American Academy of Pediatrics (AAP) has raised the public's awareness of the danger of mercury exposure.[13] The AAP recommends eradicating mercury in waste by eliminating mercury-containing medical devices, including sphygmomanometers and thermometers, from medical facilities. The AAP encourages parents not to use mercury-containing thermometers at home.

In a number of cases, the use of a mercury-containing glass thermometer has caused injury.[14,15,16] Potential risks include breakage within a bodily orifice, rectal perforation, peritonitis, diarrhea, and acrodynia after breakage.[12,17] In one account a mercury-containing glass thermometer became imbedded in the floor of a child's mouth after the toddler jumped on the bed during temperature measurement.[14] The toddler experienced significant bleeding, which was brought under control with ice cubes. Surgery was needed to remove the device. Mercury exposure was clinically insignificant.

FILAC™/FasTemp™

Mercury levels in a two-year old who sustained a facial impalement with a mercury-containing thermometer were elevated; however, the child did not show any signs of mercury poisoning and, at one year post-intervention, blood levels were negligible.[16]

Although cases of rectal perforation are reported, one author contends that it occurs in less than one in two million measurements.[18] Caregivers should use caution when obtaining rectal measurements, particularly in neonates and infants, as this rare event can be associated with serious sequelae.[19] Due to the risk, in many neonatal units, axillary temperature measurement is the preferred route.

Caregivers should consider obtaining mercury levels in children with known mercury exposure or symptoms of mercury toxicity after breakage of a mercury-containing glass thermometer. Acrodynia or pink disease is diagnosed in young children with chronic mercury exposure. Symptoms include lethargy, poor memory, and pink discoloration of fingers and palms.[20] With disease progression, desquamation, pruritus, and pain can occur.[20]

Risk of infection

Hospital-acquired infection has been linked to contaminated temperature-measuring equipment.[21-25] In a position statement on infection control in physicians' offices, the AAP recommends the disinfection of temperature-measuring equipment and the use of disposable equipment, e.g., plastic sleeves, shields etc., whenever feasible.[26] Infection-control issues and cross contamination can be avoided by disinfecting any soiled thermometer and avoiding the contamination of storage boxes, which can be cleaned with either soap and water or alcohol.[26]

A number of reports have documented the transmission of hospital-acquired infection via thermometry.[21-24] Several cases of nosocomial infection in neonatal units have been tracked back to temperature-measuring devices.[23,24] In one neonatal intensive care unit (NICU), an outbreak of *Enterobacter cloacae* was isolated from a single cap of an electronic digital thermometer.[24] Interestingly, the authors reported that the cap design prohibited proper disinfection. Isolation of colonized patients and elimination of the suspect device did not prevent the spread of infection to other neonates. The unit was eventually closed; control of the outbreak occurred after the adequate disinfection of thermometers.[25]

Certain devices, such as the FILAC FasTemp (Tyco Healthcare), have incorporated technology that use digital animation to tell the operator when to "place probe cover on" when the thermometer probe is removed from the probe well to reduce the incidence of cross contamination. Integrated into the FILAC FasTemp are color-coded isolation chambers, which house the thermometer. If using this thermometer for rectal measurements, the isolation chamber is red; if for oral use, the isolation chamber is blue. Completely separate color-coded isolation chambers with individual probes, probe wells, and probe covers may help to ameliorate infectious breakouts due to cross contamination.

In an outbreak of a multiply resistant strain of *Klebsiella pneumoniae*, an NICU was closed to control further colonization and infection.[23] Contaminated breast milk, electronic thermometers, and oxygen-saturation probes were contaminated with one strain of *Klebsiella pneumoniae*. The electronic thermometers were personal equipment carried by nurses in plastic cases that were macroscopically dirty. Their use was discontinued in favor of single-use items, bringing the outbreak under control.

Other accounts of hospital-acquired infection in adults and children include the transmission of Clostridium difficile and vancomycin-resistant Enterococcus[21]

One institution, which stopped using disposable devices, due to the fear of cross contamination from caregivers' gloves, changed to tympanic thermometers. Another institution reduced the incidence of *Clostridium-difficile* diarrhea by changing from electronic to disposable devices.[22]

Different institutions have different solutions for this same problem. What is your unit's routine for disinfecting temperature-measuring devices?

Conclusion

Temperature assessment is a task performed by nurses on a routine basis. A variety of thermometers can determine body temperature in neonates and children. Selection of the appropriate device is influenced by the child's developmental stage as well as accuracy and safety considerations.

Routine involvement of biomedical engineering in calibrating thermometers is imperative. The disinfection of shared measuring devices and soiled equipment before reuse is part of routine care. When purchasing new equipment, it is imperative that caregivers consider devices that use technology which does not involve bodily fluids or has features to prevent cross contamination in pediatric patients, e.g., Tyco's FILAC FasTemp thermometer.

Nurses must obtain accurate temperature information, while protecting our patients from the risks of mercury toxicity, rectal perforation, cross contamination, and other hazards of thermometry. Cross contamination lengthens hospital stay, drives up hospital costs, and causes unnecessary morbidity.

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Monitoring Body Temperature in Critical and Acute-care Settings — Continued

device into a body orifice. The most potentially dangerous injuries are those that cause perforation of the intestinal wall, esophagus, bladder, or tympanic membrane.[4-7] Infants and small children, restless and unconscious people, and patients with indwelling temperature probes are at greatest risk for perforation. When an indwelling thermistor is left in place, e.g., during surgery, induced hypothermia, or in emergency-care units, it is necessary to tether its lead to the patient's skin and mark the reference point where the probe enters the body orifice.

Source of Iatrogenic Infection

Any time that an instrument or medical device must be shared among patients, the hazard of cross-contamination exists. The advent of disposable probe covers for oral and rectal thermometers and hand-held tympanic membrane™ thermometers may lead to complacency among caregivers, because the contact

Singapore General Hospital using a TM thermometer (GENIUS® Tyco Healthcare) for SARS screening.

point of these devices is covered. However, evidence emphasizes the need to continue decontamination procedures between usages.[8] When plastic sheaths were tested for their efficacy in protecting oral mercury-containing glass thermometers from contamination, 80% of thermometers were found to be contaminated after use, because patients' teeth had perforated the plastic coverings. Plastic probe covers or sleeves that contain latex should not be used as a precaution against latex allergy.

Even when covered by protective sleeves, the handling of these devices can transmit pathogens between patients. Examples of hospital-acquired infections are found in studies of hospital outbreaks of vancomycin-resistant *Enterococcus faecium*.[9,10] In one case, the organism was isolated repeatedly from rectal probe handles on three electronic thermometers that were used only on nonisolated patients in the intensive care unit.[9] More recently, the spread of E. faecium among seven patients in one ward was linked to a clonal strain of the same organism, which was found on the handle of a shared electronic ear-probe thermometer.[10] Cross contamination has occurred between two

geographically separate units on a hospital ward that shared equipment but not personnel.

When patients are isolated because of highly infectious disease, a thermometric device should be assigned to each individual and subjected to organism-specific disinfecting procedures before it is used on another person. Probe covers are disposed of as hazardous waste.

Preventing cross contamination from thermometers during highly contagious epidemics, such as a severe acute respiratory syndrome (SARS) outbreak, is a challenge. Thermometers are used to screen hundreds of people to detect new cases. Proper disinfection or disposal of traditional thermometers may be neither feasible nor affordable.

The thermometer was dubbed as "the single most important tool in bringing SARS under control" by the World Health Organization (WHO),[11] because of its usefulness in screening and early detection. At the same time, the likelihood that thermometers could be vectors of SARS cross contamination led manufacturers to market one-time use, disposable thermometers for "SARS kits." Examples include the 3M TempaDot Thermometer.™ The disposable thermometer may save time, because the used thermometer can be thrown away.

Tympanic membrane thermometers appear to take less time in mass screening situations because of their rapid display. To avoid cross contamination, the handle should be cleaned between patients.

Using Thermometers and Temperature Probes

- Placement of any thermometric device requires gentle insertion.
- Never force entry; gently withdraw, rotate, and guide the instrument into a path without resistance.
- Choose an alternative to oral temperature measurement when patients have oral lesions or irritated oral mucosa.
- Rough handling of tympanic membrane thermometers during placement can be painful and injure the auditory canal.
- When lubrication is indicated (e.g., for rectal or vaginal insertion), use a water-soluble, non-greasy, non-irritating lubricant, such as K-Y Jelly™.
- Rough or broken edges on plastic casings, wrinkles on plastic sheaths, or simply a lack of sufficient lubrication can traumatize the anus during rectal thermometer insertion.
- Rectal, vaginal, esophageal, or urinary bladder thermistors must be taped or attached to an external site to prevent misplacement and migration.
- An untethered thermometer, inserted in any body orifice, should never be left unattended.
- Leads, attachments, and placement of indwelling thermistors should be checked every time that a caregiver repositions a patient.

Thermometer capabilities

What do thermometers measure?

Body temperature, a thermodynamic property, defies direct measurement and must be estimated by measuring the heat content of a specific substance such as body tissue. Temperatures vary throughout the human body because the heat content of various tissues and organs varies. Body temperatures are strongly influenced by the circulation of warm blood and insulation provided by fat and superficial tissues. Skin and superficial tissues are generally cooled by the environment. The ability of vasomotor activity to change blood flow to the skin or organs contributes to rapid changes in regional body temperatures, which occur during dynamic conditions, e.g., shock, hypothermia, or fever.

Because hemodynamic and thermoregulatory alterations can cause dramatic changes in circulation to the skin, mouth, and gut, the patient's condition should dictate the site where body temperature is measured. Furthermore, the pattern of temperature change and gradients between sites can give the astute critical care nurse clues to the patient's overall condition.

Accuracy

Thermometers cannot be accurate unless they are reliable, but the converse is not true. A thermometer may provide stable, reliable measurements over time, but unless it is calibrated for accuracy, these readings will not reflect the actual temperature being measured. When available, the pulmonary artery (PA) thermometer provides the most accurate reflection of central temperature, but when unavailable, TM thermometry, using a reliable instrument and procedural skill, is a realistic alternative.

Linearity of a thermometer is important, particularly in patients with hypothermia, hyperthermia, or fever. For example, laboratory water-bath testing of eight TM thermometers from well-established manufacturers showed their accuracy in the range of 36.7° to 38.9°C (98 to 102°F). This means that temperatures above or below this level may not be accurate. In this study, three thermometers had enough accuracy, linearity, and reliability to be used in clinical studies: The GENIUS 3000A, and FIRSTEMP 2000, (Tyco Healthcare)and THERMOSCAN (Pro-1, Braun).

None of the TM manufacturers guaranteed accuracy at temperature levels commonly seen in febrile states (>39°C) and all were found to underestimate extremely high and low (<36°C) temperatures.[12] The brands of TM thermometers deemed unacceptable for clinical studies varied in linearity along the range of 36.7° to 38.9°C.

What's the right temperature?

There is no single body temperature and no ideal site for measuring body temperature for every assessment. In critical care, the primary concern has been to keep the brain and central nervous system within a safe and optimal temperature range to prevent injury and maintain vital function. Because brain temperature cannot be measured clinically, unless indwelling thermistors are in place, other "core" temperatures are measured from deep within the body.

It is erroneous to assume that there is a single core temperature and that it can be accurately estimated from readings extrapolated at another site. Each region of the body has its own temperature, which varies as cellular metabolism, tissue friction, and circulation affect heat content.

A common misconception is that there are reliable temperature differentials of about 1° F (0.2° C) between oral, rectal, and axillary measurements. This belief leads to the faulty assumption that temperature readings from one site can estimate body temperature at another by mathematical algorithm (a predetermined formula to add or subtract an expected estimated gradient).

This assumption guides the use of offsets in TM thermometers. Algorithms are programmed into settings, so a calculation can convert TM temperature readings into rectal or core readings. This assumption is flawed. Differences or gradients between body regions are easily affected by changes in circulation or vasomotor responses. During vasodilation, the gradient between skin and core temperatures are less than during vasoconstriction. Physiological shunting of blood away from the body surface during hemorrhage, hypothermia, or in stressful situations, widens the gradients considerably.

The offset feature is not reading the actual temperature from the rectum or body core. For that reason, caregivers are often confused about what they are reading and reporting. When an abnormal temperature, based on an estimated value, is reported to a physician, unwarranted treatment may follow. When the site, type of thermometer, and any offset or code settings are reported, the physician may request a secondary temperature source or additional assessment before instituting treatment.

Predictive electronic thermometers use another type of offset estimate, which is programmed into the thermometer during manufacture.[13] These thermometers display an estimated rather than actual temperature value, while waiting for the actual temperature to equilibrate. The predicted values are determined by clinical studies during product development. Beginning with the patient's own temperature, the electronic circuitry tracks the rise of temperature in the thermistor probe and uses the slope of rise to add the offset. The final temperature is plotted as an estimate before the actual reading is reached. Accepting the speed of an estimated prediction over the accuracy of a final reading in thermometers that require a lengthy wait before achieving a steady state is the trade-off. More controlled clinical studies

are required to validate the accuracy of predictive thermometers.[13]

Some important points to remember about the practice of estimating temperatures at various body sites are:

- Comparable clinical differences between temperature sites are only fair estimations, even when measured in a resting, afebrile person in a homeostatic state.
- In dynamic states, temperatures at various sites often do not even track together; core temperatures may rise, while temperatures in peripheral regions fall.
- In critical care, conditions that mandate continuous temperature monitoring are often dynamic. Rectal temperatures lag behind central temperatures during circulatory instability or hypothermic rewarming.
- Comparing temperatures from several sites may give helpful insights about heat distribution during dynamic states, such as rewarming or stabilizing circulation.
- Measurements from one site cannot provide the gold standard for testing the accuracy of others. This practice is risky, because all body temperatures are only estimates of existing temperatures.

Measuring central temperatures

Increasingly, central temperature is used to determine which temperatures affect the heart and brain. Indwelling TM thermometers estimate central temperatures well. When probes touch the TM, they have been shown to approximate the hypothalamus in animals and pulmonary artery in humans.[14] Unfortunately, these devices are hard to keep in place in active or restless patients and cases of perforated tympanic membrane make them less desirable for monitoring temperature in critical-care settings.[4,5]

Hand-held TM thermometers, which use infrared light-reflectance technology to detect heat radiated as infrared energy from the tympanic membrane, are a reliable measure of core temperature when dependable equipment is used by trained personnel. Introduced in the late 1980s, the ear thermometer has evolved to a more streamlined hand-held device.

While the hand-held TM thermometer lacks the advantage of continuous measurement, this instrument is convenient and comfortable for patients. It is handled like an otoscope. A disposable probe tip is inserted into the ear canal and aimed at the tympanic membrane. This is where training in the use of these devices becomes crucial. Unless the infrared beam has a perfect view of the tympanum (which in one study only occurred 5% of the time),[15] it is incapable of providing a reliable measurement of TM temperature (Figure 1). When staff are trained in otoscope use, they become more aware of the positioning necessary to view the eardrum. Training should include interrater reliability checks to assure competency.

Important Characteristics of Thermometers

Accuracy: ability to measure a true temperature value

Reliability: stability and reproducibility over time

Linearity: ability to measure accurately throughout the full range of specified temperatures

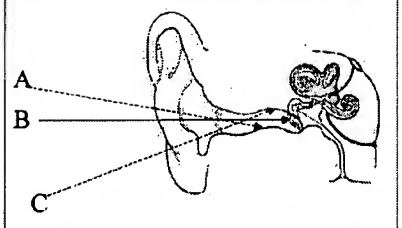
Precision: ability to detect small changes reliably in repeated measures

Esophageal temperatures are considered central temperatures because of their close proximity to the heart and large central vasculature. This site is commonly used during surgery and anesthesia.[16] There is some risk of nasopharyngeal trauma, and prolonged use has been associated with tracheoesophageal fistula.[17] Accuracy of esophageal temperature can be affected by cold or warm inhaled gases or gastric contents. Temperatures tend to increase with depth of esophageal insertion. Optimal location for probe placement is at 15 to 20 cm.[16]

Pulmonary artery temperature is the gold standard for central temperature measurement in critical-care settings. Thermistor-tipped pulmonary artery catheters that are part of advanced hemodynamic monitoring systems provide the most accurate and informative central temperature information. However, certain precautions are necessary to maintain temperature accuracy:

- Accuracy of central temperatures from the pulmonary artery depends in part on factory calibration of the monitoring system and careful handling of thermistors to prevent breakage.
- Problems with cardiac output computers contribute to faulty readings. Testing by hospital bioengineers is required at least every 6 months.

Angle of Infrared Reflection Influences Accuracy of TM Measurement



A = Elevating handle of TM probe reflects on and measures external auditory canal temperature

B = Perfect view of TM allows infrared light to reflect TM temperature

C = Lowering handle of TM probe reflects on and measures external auditory canal temperature

Figure 1

Calibration and reliability checks

Large, well-serviced institutions generally rely on a department of bioengineering to calibrate thermometric devices on a regular basis. Smaller hospitals or emergency-care centers may rely entirely on contracting out for calibration and repair. All electronic thermometers have a battery life, are sensitive to vibration, falls, and electrical interference. For this reason, these devices need a maintenance plan.

Few guidelines exist for the correct use and maintenance for thermometric equipment to ensure reliable readings. Information on how to insert and maintain indwelling thermometer probes should appear on packaging. Standards of practice, giving explicit instructions for depth of placement, lubrication, and methods of securing probes are required for consistent, safe practice. For example:

- Variations in the placement of oral thermometers affect the accuracy of readings.[21,22]
- While electronic thermometers usually signal the observer when the temperature has registered, mercury-containing glass thermometers require a waiting time of at least 3 minutes.
- Instruction in use of TM thermometers can improve the reliability and accuracy of this type of thermometry.[12] The nurse should be familiar with each type of thermometer, read the accompanying literature or instruction manuals, and follow these basic principles for troubleshooting electronic devices:
- Arrange calibration checks by a bioengineer at regular periods; enter maintenance dates on the device label.
- Use desktop calibrators when available. Keep records of calibration trends.
- Observe battery warnings and keep a record of recharging activity, as an inability to hold a charge or an erratic display may indicate the need to replace the battery.
- Remove from service any device with a hard-to-read display, cracked case, frayed or broken lead, or erratic readings.
- Do not attempt to open, adjust with a screwdriver, or otherwise fix the device.

Dynamics of temperature change

The understanding of what these changes mean are crucial to protecting critically ill patients from temperature extremes. Studies show that the site of temperature measurement becomes an important decision during unstable dynamic events. Usual temperature

gradients between sites can vary widely during shock or thermal events. For example, bladder and rectal temperatures tend to underestimate brain temperature in hyperthermic or hypothermic states.[23] To prevent temperature drift or instability during hypothermia, the temperature nearest the brain becomes more relevant. Likewise, during fever or hyperthermia, the range of temperature of critical importance is that of the brain and central nervous system.

Research shows that accurate prediction of core temperature in critically ill people cannot be achieved by measuring skin temperature with axillary or chemical dot thermometers.[24] Nurses are advised to avoid drastic gradients between skin and core temperatures that can evoke shivering.[25-27]

The following evidence-based principles of care have been developed:

- Site-specific temperature readings near the brain are most helpful in determining the threat of temperature elevation to the central nervous system.[28]
- Brain temperatures are estimated from TM and PA measurements when intraventricular thermometers are not possible.
- When wide gradients exist between brain and peripheral temperatures, maintaining a safe brain temperature is the goal.
- Peripheral temperature gradients are most helpful in determining changes in the heat distribution of patients in rewarming or hypothermic states.

Conclusion

Nurses who remain current with emerging research learn about new findings that lead to safe clinical practices. Clinical nurses should be actively involved in searching the evidence base for new information on safe and accurate temperature measurement.

There is a need to remain equally well informed about and involved with new devices. Ideally, nurses should serve on quality-assurance boards that evaluate and make purchasing decisions about these devices. Recognition of the scope, dimensions, and importance of temperature measurement is a major step toward these goals.

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This continuing education activity was approved by the Vermont State Nurses Association, Inc., an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation (ANCC).

Upon completion of this offering the learner will be able to:

1. Identify injury hazards posed by thermometry devices in contact with the patient.
2. Discuss how thermometers can be a source of iatrogenic infections.
3. Compare and contrast direct temperature measurement with estimated or algorithm-derived measurements.
4. Describe four common temperature assessment routes used in neonates and children.
5. Describe three potential routes of cross contamination when using thermometry devices.
6. List three ways to decrease the risk of cross contamination in neonatal and pediatric thermometry.

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1. **Where is the body's temperature control center?**
   a. Right atrium
   b. Hypothalmus
   c. Brain stem
   d. Carotid artery

2. **Which of the following chemicals historically used in thermometry measurement may be banned from sales?**
   a. Mercury
   b. Lead
   c. Titanium
   d. Chromium

3. **Which of the following is a reason why oral thermometry devices are often not effective in neonates or infants?**
   a. Underdeveloped sublingual vessels
   b. Anatomically relative short distance to reach sublingual pocket
   c. Unable to create a seal with mouth around thermometry device
   d. Risk of aspiration

4. **Which of the following can affect tympanic membrane thermometry measurements?**
   a. Acute otitis media
   b. Serous otitis media
   c. Improper placement of probe
   d. Wax in ear canal

5. **All of the following are ways to decrease risk of cross contamination in thermometry between patients, EXCEPT:**
   a. Use disposable probe covers
   b. Use color coded chambers: red for rectal, blue for oral
   c. Wash hands frequently
   d. Disinfect thermometer device each day

6. **Transmission of which of the following bacteria has been reportedly linked to thermometer related cross contamination in hospitalized patients?**
   a. *Pseudomonas aeruginosa*
   b. *Streptococcus pneumoniae*
   c. *Haemophilus influenzae*
   d. *Enterobacter cloacae*

7. **Benefits to axillary temperature measurements include which of the following?**
   a. Less than two seconds required to obtain accurate reading
   b. Close to hypothalamus
   c. Often widely accepted route of measurement in toddlers and young children
   d. Appropriate axillary thermometer placement occurs > 95% of the time

8. **Mercury-in-glass thermometers are:**
   a. the gold standard for accuracy in clinical thermometers.
   b. no longer used in any US clinical facility.
   c. potential sources of injury through breakage and toxicity of mercury.
   d. easier to read than digital thermometers.

9. **Plastic sheaths used on oral thermometers:**
   a. have eliminated cross-contamination between patients.
   b. make it unnecessary for the caregiver to wash hands between patients while taking vital signs.
   c. are rigid enough to guard against perforation and contamination.
   d. do not eliminate need for decontamination procedures between thermometer usage.

10. **Temperature is which of the following?**
    a. an actual entity that can be measured directly by the right thermometer
    b. a thermodynamic property of something that cannot be measured directly
    c. a conceptual model of desired warmth or coolness
    d. a characteristic that depends on sensory ability

11. **Which of the following is most influential in influencing the body temperature measured at a particular site?**
    a. Regional circulation of blood
    b. Relative of the patient
    c. pH of the urine
    d. State of the patient's consciousness

12. **Why is it important to know a thermometer's linearity with regard to its accuracy limits?**
    a. This guarantees the readings from a thermometer will stay in line during indwelling temperature measurement
    b. Lack of linearity at either end of guaranteed accuracy limits cautions the user that temperatures above or below this level may not be accurate.
    c. This characteristic tells what substances the thermometer is made of.
    d. Linearity helps to predict how often a temperature should be measured.

13. **Which of the following is correct with regard to estimating temperatures in one site from measurements taken in another?**
    a. The algorithms in tympanic membrane thermometers can estimate core or rectal temperatures with precision and accuracy.
    b. Since there is just one "core" temperature," measurements from one body cavity can be estimated from another.
    c. Temperature differentials of about 1° F (0.2° C) between oral, rectal, and axillary measurement sites are stable so estimations in algorithms are extremely reliable.
    d. Temperature differentials are unreliable in hemodynamically unstable conditions or during thermodynamic changes such as fever, hypothermia, or heat-illnesses.

14. **Under what circumstances do peripheral temperatures provide important information for planning safe patient care?**
    a. Gradients between peripheral and core temperatures are most helpful in determining changes in heat distribution of patients in rewarming or hypothermic states.
    b. Peripheral temperatures are as reliable as core temperatures to detect dangerously low hypothermic temperatures.
    c. Peripheral temperatures are of no use clinically.
    d. Peripheral temperatures from skin or axillary thermometer measurements can reliably monitor the patient during heat related illnesses, such as heat stroke.

What is the highest degree you have earned (circle one) ? 1. Diploma 2. Associate 3. Bachelor's 4. Master's 5. Doctorate

Indicate to what degree you met the objectives for this program: Using 1 = Strongly disagree to 6 = strongly agree rating scale, please circle the number that best reflects the extent of your agreement to each statement.

	Strongly Disagree					Strongly Agree
1. Identify injury hazards posed by thermometry devices in contact with the patient.	1	2	3	4	5	6
2. Discuss how thermometers can be a source of iatrogenic infections.	1	2	3	4	5	6
3. Compare and contrast direct temperature measurement with estimated or algorithm-derived measurements.	1	2	3	4	5	6
4. Describe four common temperature assessment routes used in neonates and children.	1	2	3	4	5	6
5. Describe three potential routes of cross contamination when using thermometry devices.	1	2	3	4	5	6
6. List three ways to decrease the risk of cross contamination in neonatal and pediatric thermometry.	1	2	3	4	5	6

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Journal List > BMJ > v.320(7243); Apr 29, 2000

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BMJ. 2000 April 29; 320(7243): 1174–1178.

Temperature measured at the axilla compared with rectum young people: systematic review

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Contributors: JVC wrote the protocol, participated in the review process, and drafted and revi as guarantor for the paper. GAL and PRW assisted in the design of the study, the meta-analys paper. GAL participated in the data extraction and data checking. Catherine Lees assisted in a inclusion and study quality. RLS conceived the idea, helped design the study, and assisted in final paper. All authors commented on drafts of the paper.

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Abstract

Objective

To evaluate the agreement between temperature measured at the axilla and rect young people.

Design

A systematic review of studies comparing temperature measured at the axilla (t temperature measured at the rectum (reference site) using the same type of mea sites in each patient. Devices were mercury or electronic thermometers or indw probes.

Studies reviewed

40 studies including 5528 children and young people from birth to 18 years.

Data extraction

Difference in temperature readings at the axilla and rectum.

Results

20 studies (n=3201 (58%) participants) had sufficient data to be included in a n was significant residual heterogeneity in both mean differences and sample star within the groups using different devices and within age groups. The pooled (ra temperature difference (rectal minus axillary temperature) for mercury thermon (95% limits of agreement −0.15°C to 0.65°C) and for electronic thermometers to 1.90°C). The pooled (random effects) mean temperature difference (rectal m temperature) for neonates was 0.17°C (−0.15°C to 0.50°C) and for older childr was 0.92°C (−0.15°C to 1.98°C).

Conclusions

The difference between temperature readings at the axilla and rectum using eith electronic thermometers showed wide variation across studies. This has implica situations where temperature needs to be measured with precision.

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Introduction

The presence of fever in children and young people affects the decisions of par Parents may take vigorous steps to lower their child's temperature and will com advice,[1] and clinicians may carry out investigations and interventions, including physical cooling measures, antibiotics, and admission to hospital.[2] Measuring t can be difficult, especially when they are uncooperative or restless. Measureme temperature is frequently preferred over other ways of taking temperature but n to children and parents.[2] The axilla is a safe and accessible site but concerns ha its accuracy.[3,4] We therefore systematically reviewed the agreement between te at the axilla and temperature measured at the rectum.

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Search strategy

Studies were identified by a single reviewer (JVC) through electronic searches Medline 1966 to October 1999, CINAHL 1982 to August 1999, the British Nur the *Cochrane Library* (issue 3, 1999), and the journals database of the Royal C 1985-99. The National Research Register (issue 2, 1999) was searched for any and conference abstracts were accessed through the BIDS index to Scientific ar Proceedings (1982-99). Authors of studies and suppliers of clinical thermomete provide details of other studies.

Inclusion criteria

Two reviewers (JVC and Catherine Lees) independently judged the studies for to predetermined criteria. We included: method comparison studies where temp

the axilla (test site) was compared with temperature measured at the rectum (re: same individual; studies of children and adolescents from birth to 18 years; and mercury or electronic thermometers or thermocouple probes.

We excluded children with hypothermia (rectal temperature less than 35.0°C),] than 37 weeks' gestational age), studies using different types of devices at the t where the rectal mercury thermometer was read before three minutes had elaps contacted to clarify placement times).[5,6]

Data extraction and quality assessment

Two reviewers (JVC and Catherine Lees) independently assessed studies for m As there is no validated scoring system for assessing the methodological qualit comparison studies, we modified a previously published checklist that had beer evaluating studies of diagnostic tests (see box).[7] There was initial disagreement was resolved by discussion. Two reviewers (JVC and GAL) independently extr outcome data were not provided, we asked the authors for the mean difference deviation of the difference between the temperature measured at the axilla and could not be provided, for the anonymised raw data. Where outcome data were mean and standard deviation of the measurements were reported for the two sit correlation coefficient, we calculated the mean and standard deviation of the di data. Correlation coefficients were not reported in several studies so we estimat studies.

Criteria and rationale for assessing methodological quality of comparison studies[7]*

- Were thermometers calibrated?†

Off the shelf thermometers have been shown to be inaccurate by at least 0.1°

- Was the placement time of the thermometer given?†

Mercury thermometers read before stabilisation underestimate body temperat

- Were all tests carried out concurrently or immediately sequentially?†

Where there is a delay between the two readings, any difference in the result be attributed to a change in actual body temperature

- Were the test and reference standard measured independently (blind) o
- Was the second reading taken before any interventions were given?

Avoids treatment paradox

- Were both tests carried out in all children regardless of the first reading

Avoids verification bias

*Criteria were graded as yes, no, or not stated.

†Additional criteria specific to temperature measurement.

Data analysis

We calculated the upper and lower 95% limits of agreement for each study.[8] W deviation of the differences was estimated with a correlation coefficient from a performed a sensitivity analysis including and excluding these studies. In a met randomised controlled trials, a pooled estimate of the relative treatment effect i: method comparison studies, systematic error (bias) and random error (limits of interest. To obtain a pooled estimate of bias, we used the usual Mantel-Haensze to combine individual study estimates of the mean difference. To obtain pooled limits of agreement, we first obtained a pooled estimate of the standard deviatic differences and then combined this with the pooled estimate of the mean differe hypothesised a priori that type of thermometer, duration of placement time at th thermometers, and age may be sources of heterogeneity, and we performed sub on these characteristics. Homogeneity of mean differences and standard deviati across studies were evaluated with the standard large sample test.[9] In the preser residual heterogeneity, we calculated pooled estimates of the mean difference a deviation of the individual differences using a random effects approach.[9] From these estimates it was possible to calculate pooled estimates of the limits of agr random effects approach. The techniques are described elsewhere (P R William communication).

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Results

Description of studies and methodological quality

Overall, 37 papers (34 in English) containing 40 method comparison studies in and young people were suitable for inclusion. Disagreement about study inclusi was resolved through discussion. Three studies were reported in two publicatio publications were each considered to contain two studies because either two dif populations were included and the results for each reported separately[16,17] or tw devices were studied in the same children.[18] The table gives a description of the dimensions of methodological quality. Disagreement between reviewers on the studies was resolved by discussion.

Outcome data were available from the article or author or were calculated for 1 participants). We estimated the standard deviation of the differences in tempera for four studies (331 (6%)) (table). The analysis and conclusions with and with these studies were similar and are included in the results.

Mean axillary temperature was always lower than mean rectal temperature. Sig was found between mean differences within device groups (mercury thermome $P<0.0001$; electronic thermometer: $\chi^2=959$, df=9, $P<0.0001$). Significant hetero between standard deviations within device groups (mercury: $\chi^2=943$, df=9, $P<0$ $\chi^2=519$, df=9, $P<0.0001$). The pooled (random effects) mean temperature differ axillary temperature) for mercury thermometers was 0.25°C (95% limits of agr 0.65°C) and for electronic thermometers was 0.85°C (−0.19°C to 1.90°C) (fig 1 mercury thermometers were ordered according to placement time at the axilla (time), and there was a tendency towards improved accuracy as placement time

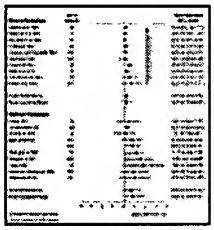


Figure 1
Mean temperature difference (rectal minus axillary temperature) and agreement by measuring device

We grouped neonates separately from other children (fig 2). Significant heterog between mean differences within the groups (neonates: $\chi^2=269$, df=9, $P<0.0001$ young people: $\chi^2=548$, df=9, $P<0.0001$). Significant heterogeneity was found b deviations within age groups (neonates: $\chi^2=111$, df=9, $P<0.0001$; older children $\chi^2=169$, df=9, $P<0.0001$). The pooled (random effects) mean temperature differ axillary temperature) for neonates was 0.17°C (−0.15°C to 0.50°C) and for old people was 0.92 (−0.15 to 1.98).

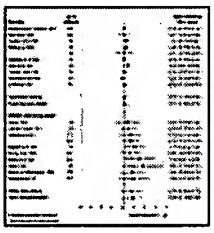


Figure 2
Mean temperature difference (rectal minus axillary temperature) and agreement by age

Of the 20 eligible studies with insufficient data (see table A on website), nine s (mercury thermometer (four studies), electronic thermometer (four), indwelling (one)), and 11 studied older children and young people (mercury thermometer (thermometer (five), and indwelling thermocouple probes (three)).

Discussion

We found large mean differences and wide limits of agreement between tempe the axilla and those measured at the rectum. Determining febrile status is an im assessment of children and young people who are unwell. Accurate measureme required in certain clinical situations or patient groups. In neutropenic patients t commence antibiotics may be made on the basis of an accurate measurement of neonates accurate measurement of temperature is important for ensuring a therm believed that rectal temperature can be estimated by adding 1°C to the temperat axilla. The wide range in the mean differences we have detected suggests that t

In general, limits of agreement were narrower when mercury thermometers we time of mercury thermometers was longer, and measurements were made in ne investigation by age was not possible because many studies reported only the a thermometers were used in only two studies of neonates. One showed narrow li The other, with wide limits of agreement, was the only study published before t different device, the telethermometer, was used.[18] Electronic thermometers wer 10 studies of older children and young people. This may have confounded the c mercury with electronic thermometers. In neonates, although agreement is bette placement times, this may be difficult to achieve. Young children may be less c placement time is prolonged, which may affect accuracy.

Review methodology

Although we used a sensitive search strategy to identify studies, we may not ha unpublished evidence. We cannot comment on the impact this may have had or of lack of empirical evidence on publication bias for method comparison studie personal communication).

The design of most studies was limited to one measurement per site per particip agreement may be caused by poor repeatability at either site. We were not able variability to see how much it differed from between site variability as data on measurements were not reported and no individual patient data were available. gave the number of febrile children by their own definition (table), but no studi separately to enable analysis of febrile children only. We did not find any evide and random error varied by level of temperature.

Methods used in primary studies

Our results may have been influenced by methodological shortfalls in the prima Verification bias was difficult to assess as selection of participants was not alwa All studies seemed to take either convenience or random samples of children fr settings. Seven studies gave specific exclusion criteria, based on clinical condit exclusion criteria. We defined verification bias to be the selecting out of partici temperature measurement. This was not evident in any study. There was no evi

the quality criteria (see box) when results were subgrouped and factors examin the number of studies in each subgroup was small.

Independent measurement of the reference standard and test was not attempted Blinding is likely to be an important methodological issue, especially when pla determined by the operator. This may occur when mercury thermometers are u thermometers are used in monitor mode rather than predictive mode. In some s in those where concurrent measurements were carried out, a different device (o used at each site. Calibration is therefore important, even when new thermomet studies did not provide details of thermometer calibration before data collectio

When a thermometer is read before stabilisation, temperature is underestimated another problem where placement time is at the discretion of the operator. Six c mercury thermometers gave details about stabilisation. Mode or placement tim out of 10 studies with electronic thermometers. In a further two studies the ther when it beeped, and it is likely that predictive mode was used. Seven studies di of placement of the rectal thermometer. In sequential studies the time lapse bet was not always reported. The longer the delay between readings, the more likel body temperature, which will affect the second reading.

We recommend that in future studies temperatures should be measured indepen a consecutive series of eligible individuals. All thermometers should be calibra provided about placement time and depth (if appropriate), steps should be take stabilisation, and the mode used in electronic thermometers should be stated. T should be carried out concurrently or immediately sequentially and the time be clearly documented. The minimum analysis that should be carried out is the Bl method[8] giving plots and 95% limits of agreement. Studies involving replicated measurements should take this into account in the analysis.

Conclusions

We have shown that in children and young people the agreement between temp the axilla and temperature measured at the rectum is relatively low. This may p fever from being detected and has important implications when body temperatu measured with precision. Further research is needed to establish whether suffici achieved by measuring temperature at the axilla in neonates. We identified sev weaknesses in the included studies, which may have affected the results.

What is already known on this topic

Numerous studies of methods for measuring temperature in children and you been carried out

Although the methods and results of the studies vary, there are concerns abou between temperature measured at the axilla and temperature measured at the

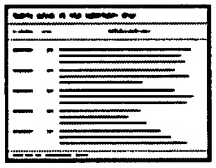
What this study adds

In children and young people temperature measured at the axilla does not agr temperature measured at the rectum to be relied on in clinical situations wher measurement is important

Variability in results was related to the age of the child and duration of placer measuring device

Research is needed to identify whether sufficient accuracy can be achieved fc temperature at the axilla in neonates

Future studies of temperature measurement in children should be more methc rigorous



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[extra: Search terms references]

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Acknowledgments

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Footnotes

Funding: JVC is supported by a grant from the Royal Liverpool Children's NHS Trust Endow

Conflict of interest: None declared.

Search terms, references, and eligible studies with missing or inappropriate data appear on th

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Infrared tympanic thermometry in the pediatric intensive care unit.

Romano MJ, Fortenberry JD, Autrey E, Harris S, Heyroth T, Parmeter P, Stein F.

Department of Pediatrics, Baylor College of Medicine, Houston, TX.

OBJECTIVES: To determine the performance of two different commercially available, noncontact infrared tympanic thermometers in predicting core body temperature as measured by pulmonary artery catheters in pediatric intensive care unit (ICU) patients. The performance of the tympanic thermometers was compared with the performance of an indwelling rectal probe and digital axillary temperature determinations. DESIGN: Prospective, consecutive sample, unblinded study. SETTING: Pediatric ICU of a tertiary care children's hospital. PATIENTS: Twenty patients requiring pulmonary artery catheter monitoring for clinical management. INTERVENTIONS: Temperature measurements were made using each infrared tympanic thermometer unit in the core mode. These values were compared with simultaneously obtained pulmonary arterial, digital axillary, and rectal probe temperatures. MEASUREMENTS AND MAIN RESULTS: Bias and variability of each method compared with the pulmonary arterial temperature were calculated. Bias did not vary with temperature measured or age of the patient. Indwelling rectal probes showed the least bias and variability and axillary temperature the most. Neither infrared tympanic thermometer had clinically important bias; one model had variability similar to that of the rectal probes, and the other model had significantly greater variability. CONCLUSIONS: In a pediatric ICU population, rectal probes reflect core temperature better than axillary determinations and both infrared tympanic models estimated core body temperature better than digital axillary temperature. One of the tympanic systems (Thermoscan Pro-1 infrared tympanic thermometer) performed in a similar way to the indwelling rectal probes and may be used to estimate core temperature in situations where a pulmonary artery catheter is not in place. The other test tympanic system (First Temp) had greater variability than the rectal probes.

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(54) Clinical thermometer for women

Klinisches Thermometer für Frauen

Thermomètre clinique pour femmes

(84) Designated Contracting States:
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AT-B- 19 552
DD-A- 141 355
DE-A- 3 606 249
GB-A- 2 092 340

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Description

The present invention relates to a clinical thermometer for women being able to effect accurate measurement of women's basal body temperature and also able to print out such data relating to birth control based on the measured basal body temperature.

There are several clinical thermometers known so far especially for women's use for measuring the basal body temperature for a certain required period and to calculate ovulation day based on the data relating to the measured basal body temperature and to indicate conceivable term being several days before and after the ovulation day.

The known women's clinical thermometer is a type to memorize the basal body temperature measured for a predetermined period, and to indicate the basal body temperature for each day unit on a display provided in the thermometer. However, it has a disadvantage in that a gynaecologist may take a little bit longer time to check the each day unit basal body temperature successively and to advise the patient accurately for birth control condition and that is difficult to exactly judge a changing date between the high temperature term and low temperature term and the ovulation day.

There are other known devices. But the operating principle or the temperature detecting algorism for the measurement of basal body temperature is rather simple. For instance, the thermometer is arranged just to memorize measured temperature immediately after a certain time lapse from the starting of the measurement of the body temperature and to take this value as the basal body temperature. Further known devices use just like the algorism of an ordinary electronic thermometer, in which a search rate temperature is previously determined from the temperature increasing curve and such a temperature is judged as the basal body temperature. Accordingly, the conventional women's clinical thermometer has a big disadvantage in that the measured basal body temperature itself is not accurate.

The present applicant had applied Japanese patent applications in this respect as follows.

(1) February 6, 1989 Application No. 26976/89 Woman's thermometer with memory functions.
(2) March 27, 1989 Application No. 74702/89 Woman's thermometer with function of calculating area of corpus luteum.
(3) May 22, 1989 Application No. 128484/89 Woman's thermometer with indicating function for birth control.
(4) July 24, 1989 Application No. 191,201/89 Woman's thermometer.

Each of the above four applications relates thermometer of rather particular use. Under the situation a thermometer having indicating function and for general use had been desired.

The present invention has for its object to solve the above mentioned problems of the prior art devices. In the present invention, an arrangement has been made to be able to accurately measure the basal body temperature in addition to print out the total birth control data related to and based on the basal body temperature measured and memorized for a certain period of time and by indicating the data by digital values or graphs so that the gynaecologist can make diagnosis properly.

It is known from United States Patent US 4530366 to provide a clinical thermometer for women comprising in combination:

calendar means arranged to output time data to other parts of the thermometer;
basal temperature determining means operative to receive the output of a temperature detecting means, operative to derive therefrom a measured temperature, and operative to derive a basal temperature,
body temperature memory means for storing on each occasion of measurement the determined basal temperature in association with output time data from the calendar means;
output means operable to provide an output signal indicative of the basal temperature and the time data stored in the body temperature memory means; and
display means operable to give, as an information item, a display of the basal temperature and the time data in accordance with said output signal. This known approach has problems of stability and accuracy.

The present invention is characterised in that the basal temperature determining means operates such that when the measured temperature has exceeded a predetermined temperature value, and thereafter the measured temperature variation over a predetermined time period lies within a predetermined range, the highest measured temperature in this time period is determined as the basal temperature,

and in that if the measurement completion time is less than a predetermined time, the temperature measurement is continued until expiry of said predetermined time and the highest temperature detected after the lapse of said predetermined time from the starting of the temperature measurement is judged as the basal body temperature.

According to the women's clinical thermometer having the above construction, the temperature measuring means recognize the detected body temperature by an input signal from the body temperature detector, and after judging a fact that the detected body temperature had exceeded a predetermined temperature and that variation of the detected body temperature lies within a preset permissible temperature range, or a time lapsed from the start of measurement of the body temperature

had exceeded a predetermined time, the highest detected temperature detected during the said predetermined period is judged as the basal body temperature. The body temperature memory means memorize the basal body temperature measured as above together with calendar date and the date of menstrual cycle. Further the indicating means display the basal body temperature memorized in the body temperature memory means by a unit of menstrual cycle and also indicate the data relating to birth control. The output means delivers out the print out signal for the printer for recording and printing out the data related to the birth control based on the basal body temperature.

For a better understanding of the invention, reference is taken to the accompanying drawings, in which:

Fig. 1 shows a panel surface diagram of the women's clinical thermometer according to the present invention, and

Fig. 2 shows a block diagram of an electronic circuit of the same women's thermometer.

The invention will now be explained by referring to the accompanying drawings.

Fig. 1 shows plan view of the panel surface of women's clinical thermometer for explaining arrangement of various parts of the device.

As can be seen from Fig. 1, on the panel surface of the women's thermometer 1 there is provided with a first indicator 2, formed of LCD (liquid crystal display), which indicates the real time in the normal indication condition with indication for AM and PM to indicate before noon or after noon. In the measuring condition of the device, this first indicator 2 acts to indicate the measured body temperature of a woman by numerals judged by a body temperature measuring algorism which will be explained in detail hereinafter. Adjacent to this first indicator 2, there is provided with a second LCD indicator 3 including a heart mark HM which will be turned on when a pregnancy condition is judged based on the basal body temperature which also will be explained later. This indicator 3 further includes an indication for the number of day in a menstruation period making the initial day of the menstruation period as the first day. Adjacent to this second indicator 3, there is a third indicator 4 which indicates in its ordinary indicating condition, the calendar month and calendar day of the day using the device and an alarm indication which operates at a preset alarm time to notify by an indication of characters "ALM" for a certain period. This portion operates to indicate the due date during turning on of said heart mark "HM" for indicating pregnancy condition and a switch 12, which will be explained later, is depressed. In said preset alarm time, a buzzer 38, which also will be explained later, operates to produce buzzer tone for a predetermined period so that the body temperature is to be measured within a term one hour before and after the buzzer tone and this temperature measuring data is memorized in a micro-computer which will be explained later.

The temperature measuring algorism for determining the basal body temperature is as follows.

(1) The detected woman's body temperature measured by a body temperature detector 30 (refer to Fig. 2) had exceeded 35°C.

(2) After exceeding 35°C of the detected woman's body temperature, the variation range of the detected temperature reached less than 0.02°C within thirty second.

(3) In the above items (1) and (2), if the detected temperature falls down more than 0.2°C, a temperature measuring error is concluded.

(4) Both the above items (1) and (2) are satisfied, a buzzer 38 (refer to Fig. 2) is energized to produce signal tone to indicate completion of the temperature measurement and the highest temperature in the above item (2) is judged as the basal body temperature and this temperature is memorized in the memory RAM (Fig. 2). However, if the above measurement completion time is less than five minutes, the temperature measurement is to be continued and the highest temperature after a lapse of five minutes from the starting of this temperature measurement is assumed as the basal body temperature and this value is memorized in the memory RAM 32 and a completion signal tone different from the above temperature measurement completion tone is produced.

Underneath the above mentioned first indicator 2, the second indicator 3 and the third indicator 4, there is provided with a graphic display 5 for indicating the basal body temperature BS of the woman by a vertical line graph measured for each successive day of the woman's menstruation period. The graphic display 5 also indicates by a horizontal line the standard temperature ST which is a mean value between the mean body temperature of the lower temperature period and the mean body temperature of higher body temperature period. This graphic display 5 has its indicating portion formed of LCD dots. Each indicating line for BS corresponds to each successive day of a menstruation period and extends in vertical direction and having, for instance, 27 dots, of which each dot corresponding to 0.05°C unit, for instance. At about middle of the vertically extending temperature indicating dots, there is one horizontal dot line for indicating the standard temperature ST. Further, under the temperature indicating dots for BS, there is a birth control period indicating dot BC extending in one horizontal line.

At upper side of the body temperature indicating dots (BS), there are memo indicating dots MD, i.e. MEMO-1, MEMO-2, --- MEMO-6, arranged in one lateral row. These memo dots MEMO-1 to MEMO-6 are used to indicate memory items being important predetermined diagnostic information for the gynaecologist in

the diagnosis and guidance for women relating to control of conceiving. This information is for instance, bleeding condition, meno-rrhagia, discharge from the womb (hereinafter simplified by discharge), sexual intercourse, attack of fever, doping of drugs like ovulation promoter, etc. Such information can be memorized by operating corresponding keys or switches each provided for each items. In order to individually indicate the above memo items of the above memo indicating dots MD, indication of MEMO-1, MEMO-2, MEMO-3, MEMO-4, MEMO-5 and MEMO-6 are provided at top outside of the graphic display 5 as shown in Fig. 1. The indication may mean by followings.

MEMO-1 ----- bleeding
MEMO-2 ----- meno-rrhagia
MEMO-3 ----- discharge
MEMO-4 ----- intercourse
MEMO-5 ----- fever
MEMO-6 ----- doping

At right hand of the graphic display 5 there are arranged various controlling push button switches.

As can be seen from Fig. 1, said controlling push button switches are arranged in two columns each having six switches and altogether twelve switches. At the top of the columns, a switch 11 for setting calendar "month' and a switch 12 for setting calendar "day" are arranged. Below this row, a switch 13 for setting "hour" in 24 hour indication and a switch 14 for setting "minute" are arranged. Further below this row, a switch 15 for setting "hour" of alarm time for notifying a time to measure the body temperature to a person under supervision by alarm and a switch 16 for setting "minute" of the alarm time. Also a left shift switch 17 for shifting the measured body temperature displayed by the graph line BS on the graphic display 5 at each periodical day towards left and a right shift switch 18 to shift the display towards right at each day by day.

Furthermore, six control switches are arranged as shown in Fig. 1. These switches are as follows.

call switch ----- 19
memory switch ----- 20
memory correct switch ----- 21
check switch ----- 22
cancel switch ----- 23
mode switch ----- 24.

A call switch 19 located at extreme bottom right is used to call the measured temperature data memorized in the RAM 32 of a micro-computer 31 which will be explained hereinafter for a week unit by each file by file beginning from the newest file and to indicate the content of the file by the line graph BS on the graphic display 5 so as to place in "call condition". By once depressing this call switch 19, the body temperature measuring data under proceeding is called out to display it by the line graph BS. This data is displayed by making the left end line graph BS as the initial day of the menstruation and the lines towards right direction indicate that for more recent date of the cycle. When depressing the call switch 19 once more, a temperature measuring data of the previous file is indicated.

There is also a memory switch 20 as shown in the drawing. When this memory switch 20 is depressed, the date indicated on the third indicator portion 4 in the ordinary indicating condition is registered in the RAM 32 as the most recent initial day of the menstruation and the graphic display 5 becomes said call condition. However, if this date is not passed over 10 days counted from the initial day of the previous menstruation period, such date is not registered as the new initial date of the menstruation period.

When the memory correction switch 21 is depressed, the indicated date showing the first day of the most recent menstruation period on the third indicator 4 registered by said memory switch 20 will start to turn on an off. At the same time, the indicating portion for the temperature of the first indicator 2 and that for the day of a certain menstruation period of the second indicator 3 become blank and the graphic display 5 also becomes blank. At this condition, the first date of the menstruation period can be changed to the date desired by using the switches 11 and 12 and referring to the third indicator 4. After setting the desired date, the memory correction switch 21 may be depressed. Then the turning on and off of the date indication on the third indicator 4 is discontinued and this date is registered as the corrected initial date of the newly corrected term.

The check switch 22 acts as follows. When this check switch 22 is depressed in said call condition, temperature indicting dot BS on the extreme left side of the graphic display 5 starts to turn on and off at a period of 0.4 sec±0.1 sec for a duration of 5 sec±0.5 sec and corresponding data, i.e. temperature, day of the period, and the first day of the menstruation period are indicated on the first indicator 2, second indicator 3, and fourth indicator 5, respectively. When the turning on and off of the extreme left dot BS on the graphic display 5, the next dot on the right will start to turn on and off to indicate the same data as above to proceed to show successive indication until the extreme right end and the temperature, day of period and the first day of the menstruation period are likewisely indicated.

The cancel switch 23 acts to stop all the processes then undergoing and to restore to the ordinary indicating condition, when it is depressed. Also it acts to delete the most recently registered body temperature measuring data among the memorized data in RAM 32. However, this deletion is limited to a condition that the device is in the ordinary indicating condition, that the time lapsed from the most recent body temperature measurement is not exceeding more than 5 minutes±15 seconds, and that the body temperature measuring data is the first measurement within one hour before and after of said

alarm time. Furthermore, an erroneously registered memory of the first date of a menstruation period can be cancelled as far as the registered memory data is under correction condition.

The mode switch 24 acts to secure the operation of other switches 11-23 when it is depressed simultaneously with one of said other switches to make the operation of other switches definite. In other words, to eliminate an erroneous operation of said other switches when contacted unintentionally and to secure the result of operation definitely only when these switches are operated under object by backing up the controlling signal.

The thermometer 30 shown in Fig. 2 and used for measuring the body temperature of a person to be supervised has a temperature measuring switch 30S, which is to be depressed at the time to start the measurement.

Now, an electronic circuit block diagram shown in Fig. 2 will be explained.

As shown in Fig. 2, as a most essential part of the electronic circuit of the women's thermometer a micro-computer 31 is provided. This micro-computer 31 comprises a central processing unit (CPU) 31A, said RAM 32, a ROM 33 accommodating various processing programs, an input interphase 34, and an output interphase 35.

To the above mentioned input interface 34, the various switches explained in the above are connected. Also a temperature detector 30 used in the measurement of body temperature of a woman is coupled via an A/D converter 36. To this A/D converter and to the input interphase, the above mentioned temperature measuring switch 30S is connected, which is associated with and accommodated in the base of the temperature detector 30.

Whereas to the output interphase 35, an LCD driver circuit 37 is connected used to drive said first indicator 2, second indicator 3, third indicator 4 and the graphic display 5, respectively. Also a buzzer 38 to produce a buzzer tone at the alarm time or at the operation time of said switches 11-24 is connected to the output interphase 35.

The output interphase 35 comprises a printer connecting interphase for connecting printer 40 for typing out various data being input to the microcomputer 31 and memorized in it.

As for the data to be printed out by the printer 40 there are basal body temperature of maximum six periods and the measured date, first date of the menstruation period, ovulation day, date of birth control, said memo items, data for pregnancy, etc.

The function of the device to judge pregnancy based on the basal body temperature to turn on said heart mark HM, to calculate the due date based on the ovulation day and to display such data will now be explained.

Based on the measured basal body temperature, after the low temperature period when there is more than 21 days of high temperature period, the micro-computer 31 judges as pregnancy condition and turns on the heart mark HM from the 21st day until first day of the next menstruation period.

The micro-computer 31 decides the ovulation day based on the following condition.

(1) More than 7 days have lapsed from the first day of menstruation.

(2) The body temperature measured on the day is higher than the standard temperature ST and the measured body temperature is higher than the lowest body temperature in the menstruation period by 0.3°C for 3 consecutive days including the same day.

If both the above two conditions are fulfilled, 4th days counted before this day is assumed as the ovulation day and memorized in the RAM 32.

Then by taking the ovulation day decided in the above process as the first day, a calculated 266th day is deemed as the due date and it is memorized in the RAM 32. Under the condition that the heart mark HM is turned on, when said day switch 12 is depressed, the above due date is indicted on said third indicator 4.

According to the present invention, the basal body temperature can be measured accurately by the temperature measuring algorism in the temperature measuring means. Also the basal body temperature measured and memorized for a desired period and the birth control data calculated by said basal body temperature can be printed out altogether when desired and it can be displayed or recorded by digital value or graphic display. Accordingly, a woman who is the subject to check the body temperature can immediately recognize the change of basal body temperature of herself and the birth control data. The gynaecologist can provide exact diagnosis or advice based on the displayed data relating to the birth control.

Claims

1. A clinical thermometer for women comprising in combination:

   calendar means arranged to output time data to other parts of the thermometer;
   basal temperature determining means operative to receive the output of a temperature detecting means, operative to derive therefrom a measured temperature, and operative to derive a basal temperature,
   body temperature memory means for storing on each occasion of measurement the determined basal temperature in association with output time data from the calendar means;
   output means operable to provide an output

signal indicative of the basal temperature and the time data stored in the body temperature memory means; and
display means operable to give, as an information item, a display of the basal temperature and the time data in accordance with said output signal,

characterised in that the basal temperature determining means operates such that when the measured temperature has exceeded a predetermined temperature value, and thereafter the measured temperature variation over a predetermined time period lies within a predetermined range, the highest measured temperature in this time period is determined as the basal temperature,

and in that if the measurement completion time is less than a predetermined time, the temperature measurement is continued until expiry of said predetermined time and the highest temperature detected after the lapse of said predetermined time from the starting of the temperature measurement is judged as the basal body temperature.

2. A clinical thermometer according to claim 1, in which the predetermined period is 30 seconds.

3. A clinical thermometer according to claim 1 or claim 2, in which the predetermined time is 5 minutes.

4. A clinical thermometer according to claim 1, 2 or 3, in which the predetermined temperature is 35°C.

5. A clinical thermometer according to claim 1, 2, 3 or 4, in which the predetermined range is 0.02°C or less.

6. A thermometer according to any preceding claim arranged to provide an alarm at a preset time and to store the basal temperature within one hour before and after said preset time.

7. A thermometer according to any preceding claim wherein said display means provides, as an information item, a graphic display (5) of basal temperature (BS) for each successive day of the woman's menstruation period.

8. A thermometer according to any preceding claim, further comprising processing means for calculating data related to birth control based on the content of said body temperature memory means.

9. A thermometer according to any preceding claim having means for entering and storing the first day of menstruation, and further comprising

means for calculating from the stored basal temperature and time data a standard body temperature which is an average of the average basal temperature in the low temperature phase and the average basal temperature in the high temperature period of the present menstrual cycle, and
detecting when the basal temperature is higher than the standard body temperature and higher than the lowest temperature of the menstrual cycle over a predetermined number of days including the present day, and
detecting when a predetermined number of days have lapsed from the first day of the present menstrual cycle, and judging ovulation day from both detected outputs.

10. A thermometer as claimed in claim 9 and further comprising

means arranged for detecting a condition of pregnancy after said ovulation day has been judged by being responsive to the occurrence of more than a predetermined number of days of high temperature of the present menstrual cycle following the low temperature phase of the present menstrual cycle as indicating that pregnancy has commenced.

11. A thermometer according to claim 10 and further comprising due date calculating and displaying means for calculating and displaying, as an information item, the due date once pregnancy has been detected.

12. A thermometer according to any one of claims 9 to 11 and further comprising

birth control period setting and displaying means for setting and displaying, as an information item, a birth control period having a predetermined relation to the ovulation day as judged by the ovulation day judging means.

13. A thermometer according to any preceding claim and comprising printing means for receiving and printing out the birth control data related to the basal body temperature.

Patentansprüche

1. Klinisches Thermometer für Frauen, umfassend in Verbindung:

Kalendermittel, die so angeordnet sind, daß Zeitdaten an andere Teile des Thermometers ausgegeben werden;

Basaltemperaturbestimmungsmittel, wirksam, um die Ausgabe eines Temperaturermittlungsmittels zu empfangen, wirksam, um davon eine gemessene Temperatur abzuleiten, wirksam, um eine Basaltemperatur abzuleiten,

Körpertemperaturspeichermittel zum Speichern der ermittelten Basaltemperatur bei jeder Messung in Verbindung mit vom Kalendermittel ausgegebenen Zeitdaten;

Ausgabemittel, wirksam um ein Ausgabesignal zu schaffen, welches die Basaltemperatur und die Zeitdaten, die im Körpertemperaturspeichermittel gespeichert sind, anzeigt,

Darstellungsmittel, wirksam um als ein Informationselement eine Anzeige der Basaltemperatur und der Zeitdaten in Übereinstimmung mit dem Ausgabesignals zu geben,

dadurch gekennzeichnet, daß

das Basaltemperaturbestimmungsmittel so arbeitet, daß, wenn die gemessene Temperatur einen vorbestimmten Temperaturwert überschritten hat und danach die gemessenen Temperaturabweichung über eine vorbestimmte Zeitspanne innerhalb eines vorbestimmten Bereichs liegt, die höchste gemessene Temperatur dieser Zeitspanne als die Basaltemperatur festgelegt wird,

und daß, wenn die Messungsabschlußzeit kürzer als eine vorbestimmte Zeit ist, die Temperaturmessung bis zum Ablauf der vorbestimmten Zeit fortgesetzt wird und die höchste Temperatur, die nach dem Ablauf der vorbestimmten Zeit vom Beginn der Temperaturmessung an ermittelt wurde, als die Körperbasaltemperatur gewertet wird.

2. Klinisches Thermometer nach Anspruch 1, in welchem die vorbestimmte Zeit 30 Sekunden beträgt.

3. Klinisches Thermometer nach Anspruch 1 oder Anspruch 2, in welchem die vorbestimmte Zeit 5 Minuten beträgt.

4. Klinisches Thermometer nach Anspruch 1, 2 oder 3, in welchem die vorbestimmte Temperatur 35°C beträgt.

5. Klinisches Thermometer nach Anspruch 1, 2, 3 oder 4, in welchem der vorbestimmte Bereich 0,02°C oder weniger beträgt.

6. Thermometer nach jedem vorhergehenden Anspruch, so ausgestattet, daß ein Alarm zu einer voreingestellten Zeit ausgelöst wird und die Basaltemperatur innerhalb einer Stunde vor und nach der voreingestellten Zeit gespeichert wird.

7. Thermometer nach jedem vorhergehenden Anspruch, worin das Darstellungsmittel als ein Informationselement eine graphische Darstellung (5) von Basaltemperatur (BS) für jeden aufeinanderfolgenden Tag der Menstruationsperiode der Frau schafft.

8. Thermometer nach jedem vorhergehenden Anspruch, welches weiter Verarbeitungsmittel umfaßt zum Berechnen von Daten, die sich auf Empfängnisverhütung, basierend auf dem Inhalt des Körpertemperaturspeichermittels, beziehen.

9. Thermometer nach jedem vorhergehenden Anspruch, welches Mittel zu Eingabe und Speicherung des ersten Tages der Menstruation aufweist und weiter umfaßt:

Mittel zum Berechnen einer Normalkörpertemperatur aus der gespeicherten Basaltemperatur und den Zeitdaten, welche ein Durchschnitt der durchschnittlichen Basaltemperatur in der Niedertemperaturphase und der durchschnittlichen Basaltemperatur in der Hochtemperaturphase des laufenden Regelzyklusses ist, und

zum Ermitteln, wenn die Basaltemperatur höher als die Normalkörpertemperatur und höher als die niedrigste Temperatur des Menstruationszyklusses über eine vorbestimmte Anzahl von Tagen unter Einschluß des gegenwärtigen Tages ist, und

zum Ermitteln, wann eine vorbestimmte Anzahl von Tagen vom ersten Tag des gegenwärtigen Regelzyklusses an vergangen ist, und

zum Bestimmen des Tages des Eisprungs aus beiden ermittelten Ergebnissen.

10. Thermometer nach Anspruch 9 und weiter umfassend:

Mittel, bestimmt zum Ermitteln eines Zustands von Schwangerschaft, nachdem der Eisprungtag ermittelt worden ist, durch Ansprechen auf das Auftreten von mehr als einer vorbestimmten Anzahl von Tagen mit hoher Temperatur des gegenwärtigen Regelzyklusses, die der Niedertemperaturphase des gegenwärtigen Regelzyklusses folgen, als Zeichen dafür, daß die Schwangerschaft begonnen hat.

11. Thermometer nach Anspruch 10 und weiter umfassend entsprechende Datenberechnungs- und Datendarstellungsmittel zum Berechnen und Darstellen, als ein Informationselement, des erwarteten Geburtsdatums, sobald die Schwangerschaft erkannt worden ist.

12. Thermometer nach jedem der Ansprüche 9 bis 11 und weiter umfassend:

    Empfängnisverhütungsperiodenfestlege- und -anzeigemittel zum Festlegen und Anzeigen, als ein Informationselement, der Empfängnisverhütungsperiode, welche einen vorbestimmten Bezug zum Eisprungtag, wie durch das Eisprungtagbestimmungsmittel ermittelt, aufweist.

13. Thermometer nach jedem vorangehenden Anspruch und umfassend Druckmittel zum Empfangen und Ausdrucken der auf die Körperbasaltemperatur bezogenen Empfängnisverhütungsdaten.

Revendications

1. Thermomètre clinique pour femmes comprenant, en combinaison :

   des moyens formant calendrier configurés de façon à délivrer des données de temps à d'autres parties du thermomètre ;
   des moyens de détermination de température basale, agissant de façon à recevoir la sortie de moyens de détection de température, agissant de façon à dériver de celle-ci une température mesurée, et agissant de façon à dériver une température basale,
   des moyens formant mémoire de température corporelle pour mémoriser à chaque occasion de mesure la température basale déterminée en association avec les données de temps délivrées en sortie par les moyens formant calendrier ;
   des moyens de sortie pouvant fonctionner de façon à délivrer un signal de sortie indicatif de la température basale et des données de temps mémorisées dans les moyens formant mémoire de température corporelle ; et
   des moyens d'affichage pouvant fonctionner de façon à donner, à titre d'élément d'information, un affichage de la température basale et des données de temps en fonction dudit signal de sortie,

   caractérisé en ce que les moyens de détermination de température basale fonctionnent de telle sorte que, lorsque la température mesurée a dépassé une valeur de température prédéterminée, et qu'ensuite, la variation de température mesurée pendant une période de temps prédéterminée est comprise à l'intérieur d'une plage prédéterminée, la température mesurée la plus élevée au cours de cette période de temps soit déterminée comme étant la température basale,

   et en ce que, si le temps d'achèvement de mesure est inférieur à un temps prédéterminé, la mesure de température est poursuivie jusqu'à l'expiration dudit temps prédéterminé, et la température la plus élevée détectée après l'écoulement dudit temps prédéterminé à partir du départ de la mesure de température est considérée comme étant la température corporelle basale.

2. Thermomètre clinique selon la revendication 1, dans lequel la période prédéterminée est de 30 secondes.

3. Thermomètre clinique selon la revendication 1 ou la revendication 2, dans lequel le temps prédéterminé est de 5 minutes.

4. Thermomètre clinique selon la revendication 1, 2 ou 3, dans lequel la température prédéterminée est de 35°C.

5. Thermomètre clinique selon la revendication 1, 2, 3 ou 4, dans lequel la plage prédéterminée est de 0,02°C ou moins.

6. Thermomètre selon l'une quelconque des revendications précédentes, configuré de façon à délivrer une alarme à un instant prédéterminé et à mémoriser la température basale pendant une heure avant et après ledit instant prédéterminé.

7. Thermomètre selon l'une quelconque des revendications précédentes, dans lequel lesdits moyens d'affichage délivrent, à titre d'élément d'information, un affichage graphique (5) de la température basale (BS) pour chaque jour successif de la période de menstruation d'une femme.

8. Thermomètre selon l'une quelconque des revendications précédentes, comprenant de plus des moyens de traitement pour calculer des données concernant le contrôle des naissances en fonction du contenu desdits moyens formant mémoire de température corporelle.

9. Thermomètre selon l'une quelconque des revendications précédentes, comprenant des moyens pour entrer et mémoriser le premier jour de menstruation, et comprenant de plus :

des moyens pour calculer à partir de la température basale mémorisée et des données de temps une température corporelle standard qui est une moyenne de la température basale moyenne dans la phase de basse température et de la température basale moyenne dans la période de haute température du cycle menstruel actuel, et
pour détecter le moment où la température basale est supérieure à la température corporelle standard, et supérieure à la température la plus basse du cycle menstruel pendant un nombre de jours prédéterminé comprenant le jour actuel, et
pour détecter le moment où un nombre de jours prédéterminé s'est écoulé à partir du premier jour du cycle menstruel actuel, et estimer le jour d'ovulation à partir des différentes sorties détectées.

10. Thermomètre selon la revendication 9, et comprenant de plus :

des moyens configurés pour détecter une condition de grossesse après que ledit jour d'ovulation ait été estimé, en réagissant à l'apparition de plus d'un nombre de jours prédéterminé de température élevée du cycle menstruel actuel suivant la phase de basse température du cycle menstruel actuel, en indiquant qu'une grossesse a commencé.

11. Thermomètre selon la revendication 10, et comprenant de plus des moyens de calcul et d'affichage de date exacte pour calculer et afficher, à titre d'élément d'information, la date exacte à partir du moment où la grossesse a été détectée.

12. Thermomètre selon l'une quelconque des revendications 9 à 11, et comprenant de plus :

des moyens d'établissement et d'affichage de contrôle des naissances pour établir et afficher, à titre d'élément d'information, une période de contrôle des naissances ayant une relation prédéterminée avec le jour d'ovulation estimé par les moyens d'estimation de jour d'ovulation.

13. Thermomètre selon l'une quelconque des revendications précédentes, et comprenant des moyens d'impression pour recevoir et imprimer les données de contrôle des naissances liées à la température corporelle basale.

FIG_1

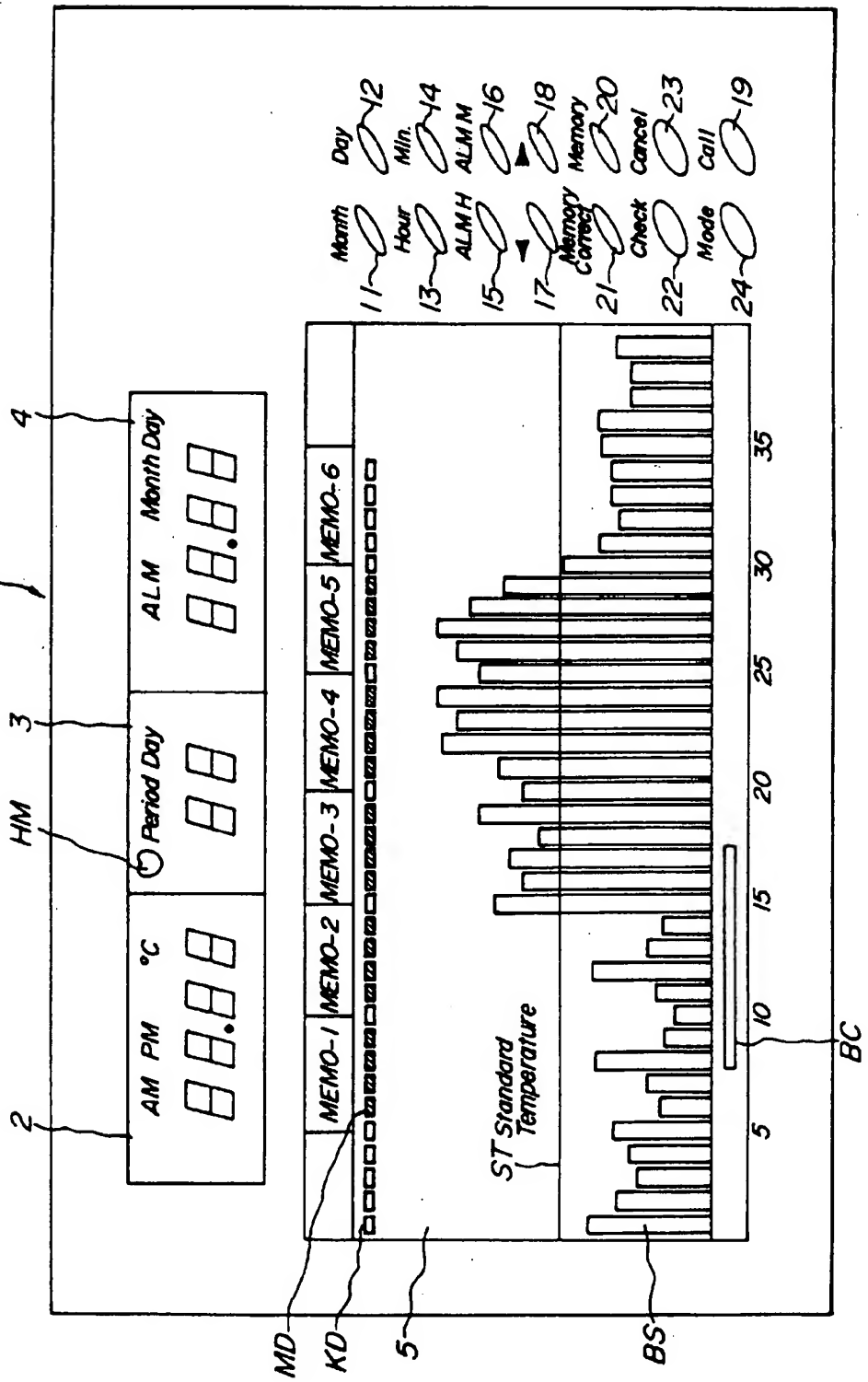
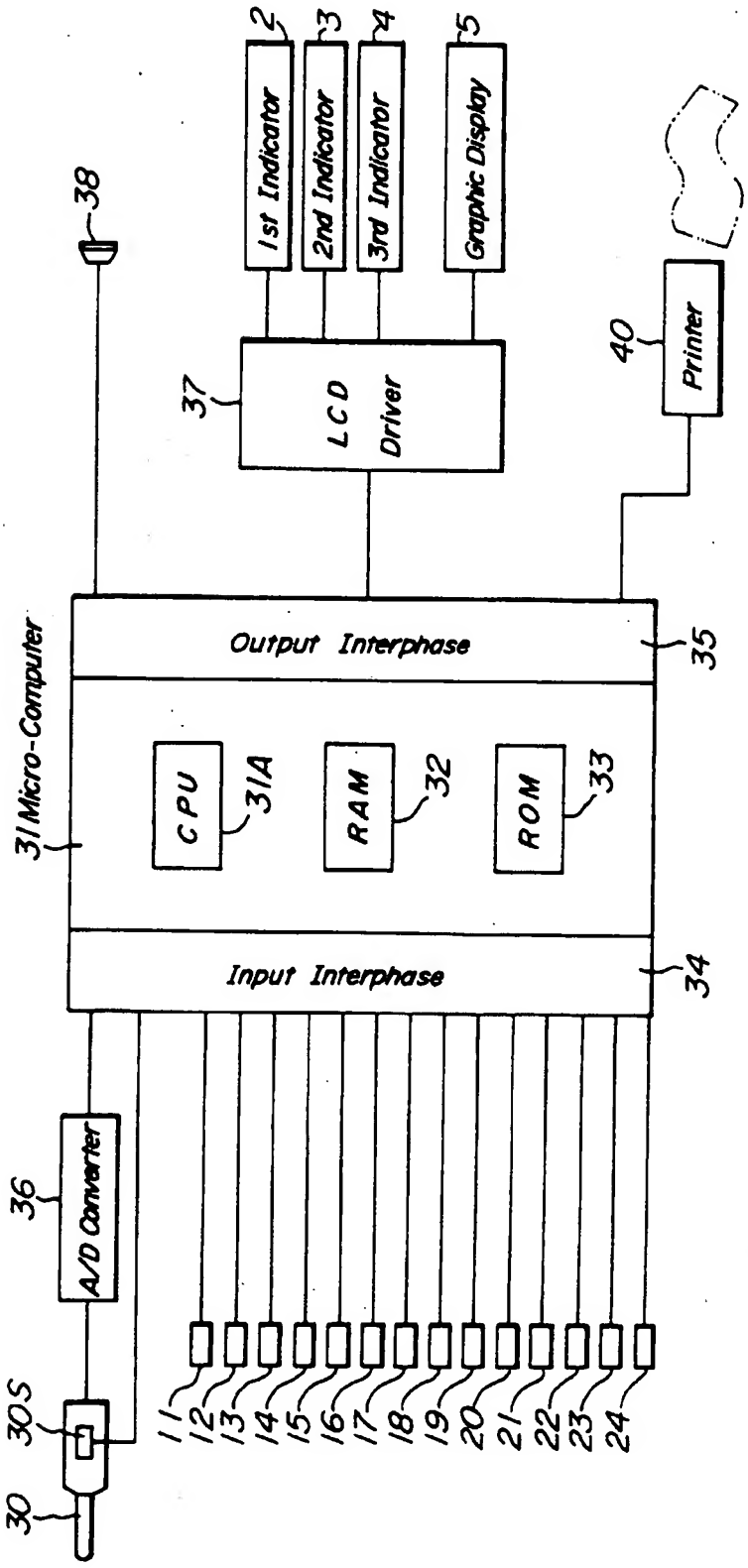

1
2
3
4
AM PM °C
Period Day
ALM Month Day
H/M
MEMO-1
MEMO-2
MEMO-3
MEMO-4
MEMO-5
MEMO-6
ST Standard Temperature
Month
Hour
ALM H
Memory Correct
Check
Mode
Day
Min.
ALM M
Memory
Cancel
Call
11
13
15
17
21
22
24
12
14
16
18
20
23
19
5
10
15
20
25
30
35
BC
MD
KD
5
BS

FIG_2


2
3
4
5
1st Indicator
2nd Indicator
3rd Indicator
Graphic Display
38
37
LCD Driver
40
Printer
Output Interphase
35
31 Micro-Computer
CPU
31A
RAM
32
ROM
33
Input Interphase
34
36
A/D Converter
30S
30
11
12
13
14
15
16
17
18
19
20
21
22
23
24